

Vascular complications in patients who underwent endovascular cardiac procedures: multicenter cohort study*

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Objective: to analyze vascular complications among patients who underwent endovascular cardiac procedures in the hemodynamic laboratories of three referral centers. **Method:** a multicenter cohort study was conducted in three referral facilities. The sample was composed of 2,696 adult patients who had undergone elective or urgent percutaneous cardiac procedures. The outcomes were vascular complications, such as: hematoma at the site of the arterial puncture; major or minor bleeding; surgical correction for retroperitoneal hemorrhage; pseudoaneurysm; and arteriovenous fistula. **Results:** 237 (8.8%) of the 2,696 patients presented a vascular complication at the site of the arterial puncture. The total number of vascular complications was 264: minor hematoma <10cm (n=135); stable bleeding (n=86); major hematoma ≥10cm (n=32); and unstable bleeding (n=11). There were no retroperitoneal hematoma events, pseudoaneurysm or arterial venous fistula. Most of the major and minor complications occurred in the first six hours after the procedure. **Conclusion:** the results concerning the current context of interventional cardiology indicate that the complications predominantly occur in the first six hours after the procedure, considering a 48-hour follow-up. The staff should plan and implement preventive measures immediately after the procedures.

Descriptors: Cardiac Catheterization; Percutaneous Coronary Intervention; Risk Factors; Complications; Postoperative Complications; Nursing Care.

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Introduction

The implementation of more complex procedures and aggressive anticoagulation regimes has affected the incidence of complications among patients undergoing endovascular procedures in Hemodynamic Laboratories⁽¹⁻³⁾. Vascular events stand out among the most frequent complications, such as bleeding at the insertion site, hematoma, pseudoaneurysm, arterial thrombosis, and distal embolization⁽⁴⁻⁷⁾.

One study addressed 11,119 patients who had undergone percutaneous coronary intervention (PCI) and 189 (1.7%) of them presented vascular complications. The following predictors of vascular complications were reported: age ≥ 70 years old (OR=2.4; $p < 0.001$); being a woman (OR=1.6, $p < 0.001$); and body mass index (BMI) (OR=5.8; $p < 0.05$)⁽⁸⁾. Other researchers addressing smaller samples identified rates of 6.5%⁽¹⁾ and 3.7%⁽⁸⁾ for vascular complications, while one of the studies also considered the use of anticoagulants (OR=3.4, $p = 0.04$), brachial access (OR=3.0, $p = 0.01$), and the long duration of exams (OR=1.4, $p < 0.001$), as being associated with the complications⁽⁹⁾.

Nevertheless, the rapid development of knowledge and wide availability of a technological arsenal in leading-edge hemodynamics laboratories, combined with the use of more powerful anticoagulation regimens, have impacted the occurrence of vascular complications in patients undergoing invasive cardiac procedures^(2,10).

From this perspective, this multicenter study takes into account this new context in which it is important to update knowledge concerning the incidence of vascular complications, in three referral facilities. This study's objective is to analyze vascular complications among patients undergoing endovascular cardiac procedures in the hemodynamics laboratories of the three referral centers.

Methods

This multicenter, prospective cohort study was conducted in three referral centers for Hemodynamics Laboratories in the south of Brazil from October 2013 to March 2014. Two are public university facilities: one has an operational capacity of 845 beds and performs approximately 280 procedures/month in the hemodynamics sector, and the other has 240 beds for hospitalization and 1,000 hemodynamics procedures/month. The third is a private facility located in the second largest city of Rio Grande do Sul, with 112 beds and approximately 110 procedures/month in the Hemodynamics Laboratory.

Patients of both sexes aged ≥ 18 years old who underwent elective or urgent endovascular procedures (cardiac catheter or PCI) through puncture of the femoral or radial artery were included. Patients lacking the clinical or mental conditions to sign free and informed consent forms or without the presence of a family companion were excluded.

Predictors of complications were identified in previous studies^(1,8-9,11-14). A convenience sample, estimated at 3,000 participants, was used. Of these, two thirds composed the derivation cohort and one third composed the validation cohort. Fletcher's⁽¹⁵⁾ recommendation of including 10 outcomes for each variable kept in the multivariate model was taken into account in the computation. Thus, for the derivation cohort to have up to eight variables in the model, considering an incidence of 3.9% vascular complications in the three facilities (unpublished data), there would be about 2,000 participants necessary. A larger incidence of complications was identified using a preliminary analysis (interim analysis) and we opted to decrease the number of individuals included without losing sample power.

The staff received training in order to standardize (1) approaching the participants; (2) obtaining the participants' signature on the free and informed consent forms; (3) the dynamics of data collection; (4) assessment and follow-up of outcomes; and (5) the recording of data on the study's forms. The research assistants, who were four undergraduate nursing students, were supervised by the head nurses of each of the facilities.

The patients were initially assessed and reassessed at the time of hospital discharge (or up to 48 hours after), either in person or by analyzing their medical files. There was no follow-up after hospital discharge. A manual containing the operational definitions of each study variable was developed.

The following outcomes were considered: 1) hematoma at the site of arterial puncture, classified according to the American College of Cardiology (ACC) classifications, large ≥ 10 cm and small < 10 cm⁽⁸⁾; 2) major bleeding, according to criteria presented by the *CRUSADE*⁽¹⁶⁾ study, defined as: documented retroperitoneal hemorrhage (without surgical correction) and any transfusion of red blood cells, with bleeding. Also, major bleeding included those with hemodynamics instability defined by uncontrolled hypertension or hypotension, tachycardia or bradycardia or decreased oxygen saturation based on previous baseline parameters, while minor bleeding included the remaining cases, without hemodynamic instability; and 3) surgical correction for any of the vascular complications of

retroperitoneal hemorrhage, pseudoaneurysm or arteriovenous fistula formation.

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) v.22. Descriptive analysis was initially performed. Continuous variables were expressed through mean and standard deviation or median (interquartile interval), according to distribution and the categorical variables were expressed in percentages and absolute numbers.

The incidence of each of the outcomes was calculated, in addition to grouping them into vascular complications or other complications. To identify the incidence of complications according to the period in which the occurrence took place, the time elapsed up to the development of complications was categorized as: (1) between zero hour and 6th incomplete hour; (b) between the 6th hour and 24th incomplete hour; and (c) between the 24th hour and 48 hours after the procedure. P-values <0.05 (two-tailed) were considered statistically significant.

This study was approved by the Institutional Review Boards at each of the facilities (HCPA 120,469, IC-FUC 114,772) and by the Unimed Hospital Management Board as recommended by resolution 466/12, which regulates research involving human subjects. All the researchers signed a document regulating the use of information collected from the patients' files.

Results

Out of a total of 2,718 potentially eligible patients, 22 were excluded: 13 for refusing to participate and nine for presenting mental confusion or hemodynamic instability at the time of data collection, lacking the presence of a family companion, so that 2,696 patients remained.

Average age was 63±11 years old and males predominated with 60%. Comorbidities, such as systemic blood pressure (SBP), Dyslipidemia, and Diabetes Mellitus (DM), were most frequently found. The sample's characteristics are presented in Table 1.

A total of 237, out of 2,696 patients, presented some type of vascular complication (8.8%). The following results refer to vascular complications analyzed according to event, considering that patients may have experienced more than one complication. The total number of complications was 264 (9.8%), distributed as follows: minor hematoma <10cm (n=135), followed by stable bleeding (n=86), major hematoma ≥10cm (n=32), and unstable bleeding (n=11). No retroperitoneal hematoma, pseudoaneurysm, or arteriovenous fistula occurred. Data presented in Figure 1.

Table 1 – Characteristics of the sample (n=2,696) of patients who underwent endovascular cardiac procedures. Caxias do Sul and Porto Alegre, RS, Brazil. 2012-2014

Variables	n (%)
Age (years)*	63±11
Sex (male)	1612 (59.8)
Cardiac catheterization diagnosis	2023 (75)
Systemic blood pressure	2281 (84.6)
Dyslipidemia	79 (72.5)
Diabetes mellitus	816 (30.3)
Kidney failure	92 (3.4)
Dialysis method	31 (1.2)
Prior hemodynamic procedure	1135 (42.1)
Prior hemodynamic vascular complication	289 (10.7)
Prior peripheral arterial disease	271 (10.1)
Prior anticoagulation	1992 (73.9)

*Variables expressed with mean ± standard deviation

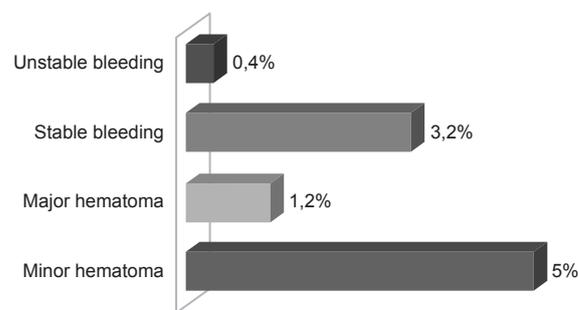


Figure 1 – Incidence of vascular complications according to type of event

Table 2 shows the incidence of complications at three different points in time: between zero hour and 6th incomplete hour; between the 6th hour and 24th incomplete hour; and between the 24th hour and 48th hour after the procedure. All the patients (n=2,696) were assessed immediately after the procedure (in the first 6 hours), while 1,349 (50.1%) and 356 (13.2%) were assessed again in the two subsequent periods, respectively. Data show that 97.3% of the major complications and 96.8% of the minor complications occurred in the first six hours after the procedure. There is a difference in the number of patients for each complication due to missing data.

"Other complications" were also investigated (vasovagal reaction, allergy, pyrogenic, arrhythmia, ischemia, embolism, and congestive and neurological complications) and 132 (4.9%) complications were found. Table 3 presents the occurrence of "other complications" stratified by subtype. A greater incidence of these complications was also observed in the first six hours after the procedure. There is also a difference in the number of patients according to type of complication due to missing data.

Two (0.1%) of the patients died, while one of the cases was potentially related to embolic complication.

Table 2 – Incidence of vascular complications from 0-6h, 6-24h, and 24-48h. Caxias do Sul and Porto Alegre, RS, Brazil. 2012-2014

Vascular complications (n)	0-6h n (%)	6-24h n (%)	24-48h n (%)	Total n (%)
Major complications (n= 2,659)	36 (1.3)	1 (<0.1)	0 (0)	37 (1.4)
Major hematoma (≥ 10cm)(n=2,667)	28 (1)	1 (<0.1)	0 (0)	29 (1.1)
Unstable bleeding (n= 2,688)	8 (0.3)	0 (0)	0 (0)	8 (0.3)
Pseudoaneurysm (n= 2,696)	0 (0)	0 (0)	0 (0)	0 (0)
Retroperitoneal hematoma (n= 2696)	0 (0)	0 (0)	0 (0)	0 (0)
Arteriovenous fistula (n= 2696)	0 (0)	0 (0)	0 (0)	0 (0)
Minor complications (n= 2,506)	184 (6.8)	5 (0.2)	1 (<0.1)	190 (7)
Major hematoma (<10cm)(n= 2,573)	118 (4.4)	4 (0.1)	1 (<0.1)	123 (4.6)
Stable bleeding (n= 2,612)	83 (3.1)	1 (<0.1)	0 (0)	84 (3.1)

Table 3 – Incidence of other immediate complications within 24h and 48h. Caxias do Sul and Porto Alegre, RS, Brazil. 2012-2014

Other complications (n)	0-6h n (%)	6-24h n (%)	24-48h n (%)	Total n (%)
Vasovagal (n= 2,627)	68 (2.5)	1 (<01)	0 (0)	69 (26)
Allergy (n= 2,664)	30 (11)	1 (<01)	1 (<01)	32 (12)
Pyrogenic (n= 2,682)	13 (05)	1 (<01)	0 (0)	14 (05)
Arrhythmia (n= 2,691)	3 (01)	2 (01)	0 (0)	5 (02)
Ischemia (n= 2,692)	1 (<01)	2 (01)	1 (<01)	4 (01)
Embolism (n= 2,694)	1 (<01)	0 (0)	1 (<01)	2 (01)
Congestive (n= 2,693)	2 (01)	0 (0)	1 (<01)	3 (01)
Neurological (n= 2,693)	2 (01)	0 (0)	1 (<01)	3 (01)

Discussion

This study presents the results of a multicenter study addressing the incidence of vascular complications in the current context of interventional cardiology. Considering all the complications addressed here (major and minor vascular complications), the percentage remained below 10%. Some studies do not address minor complications, so that, if we verify the incidence of major complications only, here defined as hematoma ≥ 10 cm, unstable bleeding, retroperitoneal hematoma, pseudoaneurysm, and arteriovenous fistula, the rate remains at 1.6%, including diagnostic and therapeutic procedures. A rate of 1.6% is relatively low, when compared to results previously reported that considered only major complications, at approximately 3%^(1,17).

One study addressing 194,476 cardiac catheterizations and 85,024 PCI procedures performed in hemodynamic laboratories, was recently published in the United States, showing that patients undergoing these procedures were progressively older, presented more comorbidities, and that their medical management after the procedures remained unchanged over the period, though there was an increasing adoption of transradial access for diagnostic procedures (from 6% to 36%; $p < 0.001$) and interventions (from 5% to 32%;

$p < 0.001$). Complications and clinical outcomes also remained constant, with a downward tendency⁽¹⁸⁾. The study addressed patients whose procedures included arterial femoral and transradial access. Attention, however, should be paid to complications, regardless of the type of access chosen, because even though transradial access has been increasingly used, many procedures are still performed using the femoral route. Thus, patients need to be continuously assessed by the nursing staff to rapidly identify events.

Another study intending to decrease the rate of vascular complications after procedures performed in the femoral artery reports that the use of fluoroscopic demarcation of the femoral head before access, small-sized introducers, and implementing the procedure in a referral center, contribute to decreasing the incidence of vascular complications⁽¹⁹⁾. The variables identified as protective factors for the non-occurrence of vascular complications are relevant, as the staff can opt to use small caliber introducers, which in fact decreases vascular complications⁽²⁰⁾.

Vascular complications most frequently took place in the first six hours after the invasive procedure, showing that the nursing staff has the opportunity to take action in order to prevent and decrease the frequency of major complications. Patients in recovery require

special attention, that is, individual and integral care⁽²¹⁻²³⁾. Nursing prescriptions in the postoperative period should include the duration of rest, verification of pulse, site of puncture, vital signs, and emphasize care concerning bleeding and hematoma. The nursing staff should be qualified to safely implement care.

When the incidence of other complications is analyzed, vasovagal reaction appears as the most frequent complication, at 2.6%, a finding that is also reported by other studies⁽⁹⁾. A study recently conducted to predict the risk of vasovagal reaction among patients who underwent PCI, reports an incidence of 4.5%, the independent factors included being a woman, primary coronary angioplasty, SBP, more than two stents implanted in the anterior descending artery, and puncture at the femoral site⁽²⁴⁾. When patients who underwent cerebral angiography exclusively using the femoral access are included, indexes vary little (4.09%)⁽²⁵⁾. Despite its low incidence, when compared to other complications, vasovagal reaction should not be underestimated, given the risk of cardiorespiratory arrest. Thus, it should be addressed in training programs and be constantly supervised by the nursing staff.

Similar to previous studies, allergy was not a very frequent event^(9,26-27). Hypersensitive responses should be taken into account when choosing the contrast media for procedures. A double-blind randomized study assessed the nonionic contrast, iso-osmolar, and low-osmolarity ionic contrast and verified that hypersensitive responses (2.5% vs. 0.7%) were statistically less frequent ($p=0.007$) in the group using the nonionic and iso-osmolar contrast media⁽²⁸⁾. Due to the use of increasingly modern contrast media with low osmolarity, allergic responses are increasingly rare, so that patient safety has advanced in this aspect.

Finally, the results found in this multicenter cohort study indicate that nurses from hemodynamic laboratories should be attentive to risk factors such as the caliber of introducer used, the prior use of anticoagulation, prior vascular complications, advanced age, being a woman, and percutaneous coronary intervention. Well-planned interventions implemented in the first six hours can change the course of patient care, improving the safety and quality of care.

Limitations for this study include the fact that procedures other than cardiac procedures performed in hemodynamics were not included.

This study's findings bring important contributions to the clinical practice of nursing staff; that is, nursing staff needs to be aware of the complications and risk factors in order to develop more efficacious care actions for their patients.

Conclusion

The results show that the general incidence of (major and minor) vascular complications in the first 48 hours in three referral centers in the south of Brazil is lower than that reported in many international referral centers. There was no occurrence of pseudoaneurysm, retroperitoneal hematoma, or arteriovenous fistula in this study. In regard to other complications, those with the highest incidence were vasovagal reactions and allergic responses.

The incidence of these complications predominantly occurred in the first six hours after the procedures, considering a 48-hour follow-up. The staff should plan preventive measures to be implemented immediately after procedures.

This study's findings contribute to knowledge concerning complications that patients undergoing endovascular cardiac procedures may experience, which can support the planning of care provided before and after procedures.

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